

1 JOHN H. GOMEZ (SBN 171485)
jgomez@gomeztrialattorneys.com
2 AHMED S. DIAB (SBN 262319)
adiab@gomeztrialattorneys.com
3 LINDSAY R. STEVENS (SBN 286511)
lstevens@gomeztrialattorneys.com
4 **GOMEZ TRIAL ATTORNEYS**
655 W. Broadway Suite 1700
5 San Diego, California 92101
Telephone: (619) 237-3490
6 Facsimile: (619) 237-3496

7 J.KYLE BACHUS (Colo. Bar No. 24441)
kyle.bachus@coloardolaw.net
8 **BACHUS & SCHANKER, LLC**
1899 Wynkoop Street, Suite 700
9 Denver, CO 80202
Telephone: (303) 893-9800
10 Facsimile: (303) 893-9900
(Pending Pro Hac Vice)

11
12 *Attorneys for Plaintiff Diane Starkey*

13
14 **UNITED STATES DISTRICT COURT**
15 **NORTHERN DISTRICT OF CALIFORNIA**
SAN FRANCISCO/OAKLAND DIVISION

16 DIANE STARKEY

17 Plaintiff,

18 v.

19 SANOFI S.A.,
20 AVENTIS PHARMA S.A., and
21 SANOFI-AVENTIS U.S. LLC

22 Defendants.
23
24
25
26
27

Case No: 16-5325

COMPLAINT FOR:

1. **Product Liability for Negligence**
2. **Strict Products Liability – Design and Manufacturing Defects**
3. **Strict Products Liability – Failure to Warn**
4. **Breach of Express Warranty**
5. **Breach of Implied Warranty**
6. **Fraudulent Misrepresentation**
7. **Fraudulent Concealment**
8. **Negligent Misrepresentation**
9. **Strict Product Liability for Misrepresentation**
10. **Fraud and Deceit**

**11. Extreme and Outrageous Conduct/
Intentional Infliction of Emotional
Distress**

DEMAND FOR JURY TRIAL

Plaintiff, Diane Starkey, by and through her attorneys, respectfully submits the following Complaint and Jury Demand against Defendants Sanofi S.A.; Aventis Pharma S.A.; and Sanofi-Aventis U.S. LLC, separately, and doing business as Winthrop U.S., and alleges the following upon personal knowledge, information and belief, and investigation of counsel.

NATURE OF THE CASE

1. This action seeks to recover damages for injuries sustained by Plaintiff as the direct and proximate result of the wrongful conduct of Defendants Sanofi S.A., Aventis Pharma S.A., and Sanofi-Aventis U.S. LLC in connection with the designing, developing, manufacturing, distributing, labeling, advertising, marketing, promoting, and selling of docetaxel (TAXOTERE®), a prescription medication used in the treatment of breast cancer.

JURISDICTION AND VENUE

2. This Court has subject matter jurisdiction pursuant to 28. U.S.C. § 1332 (diversity jurisdiction). The amount in controversy exceeds \$75,000.00 exclusive of interest and costs. There is complete diversity of citizenship between Plaintiff and Defendants. Plaintiff is a resident and citizen of and is domiciled in the State of California. As set forth more fully below, all Defendants are entities organized in states other than the State of California, all Defendants have their

1 principal place of business in a state other than the State of California, and none of
2 the Defendants is a citizen or resident of the State of California.

3 3. This Court has personal jurisdiction over Defendants, each of which
4 is licensed to conduct and/or is systematically and continuously conducting
5 business in the State of California, including, but not limited to, the marketing,
6 advertising, selling, and distributing of drugs, including TAXOTERE®, to the
7 residents in this State.

8 4. Venue is proper in this District pursuant to 28 U.S.C. § 1391(a),
9 because Defendants marketed, advertised, and distributed the dangerous product
10 in this District; Plaintiff resides in this District; Plaintiff's harms, losses, and
11 damages occurred in this District; Defendants do substantial business in the State
12 of California and within this District; and at all times relevant hereto, Defendants
13 developed, manufactured, promoted, marketed, distributed, warranted, and sold
14 TAXOTERE® in interstate commerce.

15 **PARTIES**

16 5. Plaintiff Diane Starkey is and was at all relevant times a citizen and
17 adult resident of the State of California and was prescribed and used docetaxel
18 (TAXOTERE®), which was developed, manufactured, promoted, marketed,
19 distributed, and sold by Defendants. Plaintiff has suffered damages as a result of
20 Defendants' illegal and wrongful conduct alleged herein.

21 6. Defendant Sanofi S.A. is a corporation or Société Anonyme
22 organized and existing under the laws of France, having its principal place of
23 business at 54 rue La Boétie, 75008 Paris, France.

24 7. Defendant Aventis Pharma S.A. is a corporation or Société Anonyme
25 organized and existing under the laws of France, having its principal place of
26 business at 20 avenue Raymond Aron, 92160 Antony, France.

1 8. Defendant Sanofi-Aventis U.S. LLC is a Delaware limited liability
2 company, which has its principal place of business at 55 Corporate Drive,
3 Bridgewater, New Jersey 08807. Defendant Sanofi-Aventis U.S. LLC is a
4 subsidiary of Defendant Sanofi S.A. Defendant Sanofi S.A. is the only member
5 and owns 100% of the membership interest (both financial and voting) of
6 Defendant Sanofi-Aventis U.S. LLC. Defendant Sanofi-Aventis U.S. LLC does
7 not have any members that are citizens, residents, or domiciles of the State of
8 California.

9 9. Defendant Sanofi-Aventis U.S. LLC sometimes operates, promotes,
10 markets, sells, distributes pharmaceutical products, and does business under the
11 name of Winthrop U.S., which is not a separately existing legal entity but rather is
12 a business unit or division operating within and part of Sanofi-Aventis U.S. LLC.

13 **DEFENDANTS' OWNERSHIP AND UNITY OF INTEREST**
14

15 10. Sanofi S.A. is a French multinational pharmaceutical parent company
16 that operates worldwide through a complex, consolidated, and intermingled web
17 of more than 400 wholly-owned subsidiaries, including Aventis Pharma S.A. and
18 Sanofi-Aventis U.S. LLC. As of 2013, Sanofi S.A. was the world's fifth-largest
19 pharmaceutical company by sales.

20 11. At all times relevant, Sanofi S.A. was engaged in the business of
21 researching, analyzing, licensing, designing, formulating, compounding,
22 patenting, testing, manufacturing, producing, processing, assembling, inspecting,
23 distributing, marketing, labeling, promoting, packaging, advertising, and/or selling
24 the prescription drug docetaxel (TAXOTERE®) through its numerous wholly-
25 owned subsidiaries in the United States and throughout the world, including
26 Defendants Aventis Pharma S.A. and Sanofi-Aventis U.S. LLC.

12. The predecessor to the entity now known as Sanofi S.A. was founded in 1973 as a subsidiary of Elf Aquitaine, a French oil company subsequently acquired by Total, when Elf Aquitaine took control of the Labaz group pharmaceutical company. In 1993, Sanofi entered the U.S. pharmaceutical market by first partnering with and then later acquiring Sterling Winthrop and its prescription pharmaceutical business in 1994. Sanofi was incorporated under the laws of France in 1994 as a *société anonyme*.

13. Aventis was formed in 1999 when the French company Rhône-Poulenc S.A. merged with the German corporation Hoechst Marion Roussel, which itself was formed from the 1995 merger of Hoechst AG with Cassella, Roussel Uclaf, and Marion Merrell Dow. The merged company was based in Schiltigheim, near Strasbourg, France.

14. Sanofi-Aventis S.A. was formed in 2004 with the merger of Aventis and Sanofi-Synthelabo, each of which had previously been formed through mergers. Sanofi-Aventis changed its name to Sanofi S.A. on May 6, 2011, after receiving approval at its annual general meeting. The reason given by the company for the change was to make its name easier to pronounce in other countries such as China.

15. Sanofi S.A.'s shares are listed on the New York Stock Exchange and the NASDAQ Global Market. Sanofi S.A. is required by law to register its securities in the United States under section 12(g) of the Securities Exchange Act of 1934 on Form 20-F and to file its annual reports on Form 20-F.

16. According to Sanofi S.A.'s Form 20-F filed with the U.S. Securities and Exchange Commission for the fiscal year ended December 31, 2014, Sanofi S.A. owns 100% of the membership and voting interest of Sanofi-Aventis U.S. LLC. Therefore, Sanofi S.A. controls and directs the operations of Sanofi-Aventis U.S. LLC.

1 Defendants became the alter-ego of one another and are jointly-liable for their
2 misconduct and wrongful acts as alleged herein.

3 22. As the corporate parent of these wholly-owned subsidiaries, Sanofi
4 S.A. directs and controls the operations of Aventis Pharma S.A. and Sanofi-
5 Aventis U.S. LLC. Accordingly, there exists, and at all relevant times herein
6 existed, a unity of interest, ownership, and conduct between Sanofi S.A., Aventis
7 Pharma S.A., and Sanofi-Aventis U.S. LLC with regard to the manufacture,
8 distribution, development, testing, and labeling of the docetaxel (TAXOTERE®)
9 in question and with regard to other related conduct, such that any individuality
10 and separateness between Defendants had ceased and these Defendants became
11 the alter-ego of one another.

12 23. Sanofi S.A., through its complicated web of various affiliates,
13 wholly-owned subsidiaries, and predecessor companies, including Aventis
14 Pharma S.A. and Sanofi-Aventis U.S. LLC, has been directly involved in and has
15 overseen the invention, development, clinical trials, and strategy for marketing,
16 distributing, selling, and promoting Taxotere® (docetaxel) throughout the world
17 and in the United States. Sanofi S.A. markets Taxotere® (docetaxel) worldwide in
18 over 100 different countries. When press releases are issued announcing the
19 introduction, marketing, and distribution of Taxotere® (docetaxel) in a new
20 country, the press releases are issued by Sanofi S.A., or before 2011 when Sanofi
21 S.A. changed its name, by Sanofi-Aventis.

22 **DEFENDANTS' INVOLVEMENT IN THE DEVELOPMENT,**
23 **PATENTING, TESTING, MARKETING, AND**
24 **SALE OF TAXOTERE® (DOCETAXEL)**

25 24. Docetaxel (TAXOTERE®) is a drug used in the treatment of various
26 forms of cancer, including but not limited to breast cancer. Docetaxel
27 (TAXOTERE®) is a part of a family of drugs commonly referred to as Taxanes.

1 25. Taxanes are diterpenes produced by the plants of the genus *Taxus*
2 (yews) featuring a taxadiene core. Taxanes are widely used as chemotherapy
3 agents. Taxane agents include paclitaxel (TAXOL®) and docetaxel
4 (TAXOTERE®). Taxane agents also exist as cabazitaxel and in generic forms as
5 well.

6 26. Paclitaxel (TAXOL®), which was developed, manufactured, and
7 distributed by Bristol-Myers Squibb and is the main competitor drug to docetaxel
8 (TAXOTERE®), was first approved by the U.S. Food and Drug Administration
9 (FDA) in December 1992.

10 27. The drug and chemical compound that would become known as
11 docetaxel (TAXOTERE®) was invented and developed by Michel Colin, Daniel
12 Guenard, Francoise Gueritte–Voegelein, and Pierre Potier of Rhone-Poulence
13 Santé. Docetaxel (TAXOTERE®) was designed as an increased potency Taxane.

14 28. The initial patent disclosing the formulation and computation of
15 docetaxel (TAXOTERE®) was issued to Rhone-Poulence Santé and subsequently
16 assigned to Defendant Aventis Pharma S.A in March 1989. Sanofi S.A. owns
17 100% of the shares or financial interest of Aventis Pharma S.A., and Sanofi S.A.
18 therefore directs and controls the operations and activities of Aventis Pharma S.A.
19 Since March 1989, Sanofi S.A., through its wholly-owned subsidiary, Aventis
20 Pharma S.A., has controlled the development and been the owner, holder, or
21 assignee of the patents related to docetaxel (TAXOTERE®).

22 29. In 1989, Sanofi issued the prior art publication F. Lavelle,
23 *Experimental Properties of RP 56976*, a taxol derivative. RP 56976 was the
24 number that Rhone-Polunec, Aventis Pharma S.A.'s predecessor, assigned to
25 docetaxel.

26 30. Sanofi began enrolling patients in Phase I clinical testing trials on
27 June 21, 1990. The study reporting on these trials was called the "TAX 001"

1 study, which continued until May 13, 1992. The results from the TAX 001 study
2 were reported on May 24, 1994. Accordingly, Sanofi was not only involved in the
3 patenting and assignment of the compound Taxotere® (docetaxel), but Sanofi was
4 also directly involved in the clinical trials and testing of the compound Taxotere®
5 (docetaxel). Accordingly, Sanofi S.A. and Aventis Pharma S.A. have direct and
6 personal knowledge of the results of those tests and Sanofi S.A., Aventis Pharma
7 S.A., and Sanofi-Aventis U.S. LLC's decisions to withhold information and data
8 from those tests from physicians, healthcare providers, patients, and Plaintiff in
9 the United States.

10 31. Rhône-Poulenc Rorer S.A., before it was acquired by or merged into
11 Aventis Pharma S.A., initially sought FDA approval for docetaxel
12 (TAXOTERE®) in December 1994. The FDA's Oncologic Drugs Advisory
13 Committee panel unanimously recommended the rejection of Rhône-Poulenc
14 Rorer S.A.'s request for the approval of docetaxel (TAXOTERE®), because
15 docetaxel (TAXOTERE®) was more toxic than its competing drug TAXOL®,
16 which had already received FDA approval, and because more studies of
17 docetaxel's side effects were needed.

18 32. Docetaxel (TAXOTERE®) was ultimately approved by the FDA on
19 May 14, 1996. According to its product labeling, docetaxel (TAXOTERE®) was
20 "indicated for the treatment of patients with locally advanced or metastatic breast
21 cancer after failure of prior chemotherapy."

22 33. After the initial FDA approval, Defendants sought and were granted
23 FDA approval for additional indications for docetaxel (TAXOTERE®). Based on
24 self-sponsored clinical trials, Defendants claimed superiority over other
25 chemotherapy products approved to treat breast cancer. Defendants' marketing
26 claims included claims of superior efficacy over the lower potency Taxane

1 product paclitaxel (TAXOL®), which was the primary competitor product to
2 docetaxel (TAXOTERE®).

3 34. Contrary to Defendants' claims of superior efficacy, post market
4 surveillance has shown that the more potent and more toxic docetaxel
5 (TAXOTERE®) does not in fact offer increased efficacy or benefits over other
6 Taxanes, as Defendants have claimed and advertised. Defendants concealed the
7 existence of studies from the FDA, physicians, and patients that refuted
8 Defendants' claims. A study published in 2008 in the New England Journal of
9 Medicine, titled *Weekly Paclitaxel in the Adjuvant Treatment of Breast Cancer*,
10 concluded that TAXOL® (paclitaxel) was more effective than TAXOTERE®
11 (docetaxel) for patients undergoing standard adjuvant chemotherapy with
12 doxorubicin and cyclophosphamide.

13 35. Despite the publication of this study, Defendants continued to make
14 false and misleading statements promoting the "superior efficacy" of docetaxel
15 (TAXOTERE®) over the competing product paclitaxel (TAXOL®). As a result of
16 these false and misleading statements, in 2009, the FDA issued a warning letter to
17 Sanofi-Aventis (the same company as Defendant Sanofi S.A. before Sanofi-
18 Aventis changed its name in 2011) citing these unsubstantiated claims of
19 superiority over paclitaxel stating:

20 The Division of Drug Marketing, Advertising, and
21 Communications (DDMAC) of the U.S. Food and Drug
22 Administration (FDA) has reviewed a professional
23 reprint carrier [US.DOC.07.04.078] for Taxotere
24 (docetaxel) Injection Concentrate, Intravenous Infusion
25 (Taxotere) submitted under cover of Form FDA 2253 by
26 sanofi-aventis (SA) and obtained at the American
27 Society of Clinical Oncology annual meeting in June

1 2008. The reprint carrier includes a reprint¹ from the
2 Journal of Clinical Oncology, which describes the TAX
3 311 study. This reprint carrier is false or misleading
4 because it presents unsubstantiated superiority claims
5 and overstates the efficacy of Taxotere. Therefore, this
6 material misbrands the drug in violation of the Federal
7 Food, Drug, and Cosmetic Act (the Act), 21 U.S.C.
8 352(a) and 321(n). *Cf.* 21 CFR 202.1(e)(6)(i), (ii) &
9 (e)(7)(ii).²

10 36. A Qui Tam lawsuit was also filed against Sanofi-Aventis and its
11 affiliates in the United States District Court for the Eastern District of
12 Pennsylvania by a former employee accusing Sanofi-Aventis and its affiliates of
13 engaging in a fraudulent marketing scheme, paying kickbacks, and providing
14 other unlawful incentives to entice physicians to use docetaxel (TAXOTERE®).
15 *See U.S. ex rel. Gohil v. Sanofi-Aventis U.S. Inc.*, Civil Action No. 02-2964 (E.D.
16 Pa. 2015).

17 37. Beginning in 1996, Sanofi S.A., Aventis Pharma S.A., and Sanofi-
18 Aventis U.S. LLC and their predecessors and affiliates designed, directed, and/or
19 engaged in a marketing scheme that promoted docetaxel (TAXOTERE®) for off-
20 label uses not approved by the FDA. The scheme took two forms: first,
21 Defendants trained and directed their employees to misrepresent the safety and
22 effectiveness of the off-label use of Taxotere to expand the market for docetaxel
23 (TAXOTERE®) in unapproved settings; and second, Defendants paid healthcare
24

25 ¹ Jones SE, Erban J, Overmoyer B, et al. Randomized phase III study of docetaxel compared
26 with paclitaxel in metastatic breast cancer. *J Clin Oncol.* 2005;23(24):5542-51.

27 ² Correspondence signed by Keith Olin, Pharm.D., Regulatory Review Officer in the FDA's
28 Division of Drug Marketing, Advertising and Communications to MaryRose Salvacion,
29 Director of US Regulatory Affairs Marketed Products at sanofi-aventis.

1 providers illegal kickbacks in the form of sham grants, speaking fees, travel,
2 entertainment, sports and concert tickets, preceptorship fees, and free
3 reimbursement assistance to incentivize healthcare providers to prescribe
4 docetaxel (TAXOTERE®) for off-label uses. As a direct result of Defendants'
5 fraudulent marketing scheme, Defendants dramatically increased revenue on sales
6 of docetaxel (TAXOTERE®) from \$424 million in 2000 to \$1.4 billion in 2004.
7 *U.S. ex rel. Gohil v. Sanofi-Aventis U.S. Inc.*, 96 F. Supp. 3d 504, 508 (E.D. Pa.
8 2015).

9 38. As a direct result of their wrongful conduct and illegal kickback
10 schemes, Defendants directly caused thousands of individuals to be exposed to
11 docetaxel's (TAXOTERE®) increased toxicity as compared to other available less
12 toxic products.

13 39. As a direct result of their aforementioned conduct, Defendants caused
14 thousands of individuals to be exposed to increased frequency and more severe
15 side effects, including but not limited to disfiguring permanent alopecia (hair
16 loss).

17 **DEFENDANTS' COVER UP IN THE UNITED STATES**
18 **REGARDING THE CAUSAL RELATIONSHIP BETWEEN DOCETAXEL**
19 **(TAXOTERE®) AND PERMANENT DISFIGURING HAIR LOSS**

20 40. Although alopecia, or hair loss, is a common side effect related to
21 chemotherapy drugs, permanent alopecia is not. Defendants, through their
22 publications and marketing materials, misled Plaintiff, the public, and the medical
23 community to believe that, as with other chemotherapy drugs that cause alopecia,
24 patients' hair would grow back.

25 41. Defendants knew or should have known that the rate of permanent
26 alopecia related to docetaxel (TAXOTERE®) was far greater than with other
27 products available to treat the same condition as Defendants' product.

42. Permanent baldness (permanent alopecia) is a disfiguring condition, especially for women. Women who experienced disfiguring permanent alopecia as a result of the use of docetaxel (TAXOTERE®) suffer great mental anguish as well as economic damages, including but not limited to loss of work or inability to work due to significant psychological damage.

43. Although women might accept the possibility of permanent baldness as a result of the use of docetaxel (TAXOTERE®) if no other product were available to treat their cancer, this was not the case. Before Defendants' wrongful conduct resulted in thousands of women being exposed to the side effects of docetaxel (TAXOTERE®), there were already similar products on the market that were at least as effective as docetaxel (TAXOTERE®) and did not subject female users to the same risk of disfiguring permanent alopecia as does docetaxel (TAXOTERE®).

44. Beginning in the late 1990's, Sanofi S.A. and Aventis Pharma S.A. sponsored and/or were aware of a study titled the GEICAM 9805 study. In 2005, Sanofi S.A. and Aventis Pharma S.A. knew that the GEICAM 9805 study demonstrated that 9.2% of patients who took docetaxel (TAXOTERE®) had persistent alopecia, or hair loss, for up to 10 years and 5 months, and in some cases longer, after taking docetaxel (TAXOTERE®). Sanofi S.A. and Aventis Pharma S.A. knowingly, intentionally, and wrongfully withheld these results contained in the GEICAM 9805 study from physicians, healthcare providers, patients, and Plaintiff in the United States.

45. In 2006, Defendants knew or should have known that a Denver-based oncologist in the United States had observed that an increased percentage (6.3%) of his patients who had taken docetaxel (TAXOTERE®) suffered from permanent disfiguring hair loss for years after the patients had stop taking docetaxel (TAXOTERE®).

1 46. Despite Defendants' knowledge of the relevant findings from the
2 GEICAM 9805 study, as well as reports from patients who had taken docetaxel
3 (TAXOTERE®) and suffered from permanent disfiguring hair loss, Defendants
4 failed to provide accurate information and proper warnings to physicians,
5 healthcare providers, and patients in the United States, including Plaintiff, that
6 patients who take docetaxel (TAXOTERE®) are at a significantly increased risk
7 of suffering from permanent disfiguring hair loss. Instead, Defendants chose to
8 withhold this information in the United States despite advising physicians,
9 patients, and regulatory agencies in other countries, including the European Union
10 and Canada, that docetaxel (TAXOTERE®) causes an increased risk of
11 permanent disfiguring hair loss. Defendants instead continued to warn or advise
12 physicians, healthcare providers, patients, and Plaintiff in the United States only
13 with the generic, vague, and insufficient warning that "hair generally grows back"
14 after taking docetaxel (TAXOTERE®).

15 47. Users of docetaxel (TAXOTERE®) were not presented with the
16 opportunity to make an informed choice as to whether the benefits of docetaxel
17 (TAXOTERE®) were worth its associated risks. Defendants engaged in a pattern
18 of deception by overstating the benefits of docetaxel (TAXOTERE®) as
19 compared to other alternatives while simultaneously failing to warn of the risk of
20 disfiguring permanent alopecia.

21 48. Although Defendants publish information in other countries to
22 individual patients as well as regulatory agencies related to docetaxel
23 (TAXOTERE®) and the risk of permanent alopecia, the words permanent
24 alopecia or permanent hair loss do not appear in any information published by
25 Defendants in the United States.

26 ///

27 ///

1 49. As a direct result of Defendants' wrongful and deceptive acts,
2 thousands of women were exposed to the risk of disfiguring permanent alopecia
3 without any warning and without any additional benefit.

4 50. As a direct result of Defendants' failure to warn patients of the risk of
5 disfiguring permanent alopecia in the United States, thousands of women,
6 including Plaintiff, as well as their health care providers, were deprived of the
7 opportunity to make an informed decision as to whether the benefits of using
8 docetaxel (TAXOTERE®) over other comparable products was justified.

9 51. Defendants preyed on one of the most vulnerable groups of
10 individuals at the most difficult time in their lives. Defendants obtained billions of
11 dollars in increased revenues at the expense of unwary cancer victims simply
12 hoping to survive their condition and return to a normal life.

13 52. Docetaxel (TAXOTERE®) was defective in its design. Docetaxel
14 (TAXOTERE®) was designed as an increased potency Taxane. This increased
15 potency resulted in increased toxicity, which can be directly related to increased
16 adverse events. The most likely reason Defendants designed the increased potency
17 Taxane was to enable them to obtain a patent (and the concurrent market
18 advantage) on a product that in fact was not novel but instead only more
19 dangerous.

20 53. Plaintiff Diane Starkey, as well as numerous other women, were the
21 innocent victims of Defendants' greed, recklessness, and willful and wanton
22 conduct.

23 **PLAINTIFF DIANE STARKEY'S DIAGNOSIS, TREATMENT, AND**
24 **RESULTING DISFIGURING PERMANENT ALOPECIA**

25 54. In 2002, Plaintiff was diagnosed with left breast cancer.

26 55. Following her diagnosis, Plaintiff had surgical treatment which
27 included a lumpectomy.

56. Plaintiff consulted with a medical oncologist regarding her options for chemotherapy. The oncologist was not aware, nor had he/she been informed, of any warnings from Defendants that disfiguring permanent alopecia can occur following treatment with docetaxel (TAXOTERE®).

57. Accordingly, Plaintiff underwent six cycles of chemotherapy in November 2002 through February 2003 that included docetaxel (TAXOTERE®). Plaintiff did not know or suspect until January 2016 that she was suffering from continuing hair loss as a result of taking docetaxel (TAXOTERE®). As a result of Defendants' wrongful conduct, Plaintiff has continued to suffer and will suffer in the future from disfiguring permanent alopecia as a result of receiving chemotherapy with docetaxel (TAXOTERE®).

NATURE OF THE CLAIMS

58. Despite the fact that Defendants disclosed risks associated with docetaxel (TAXOTERE®) and permanent alopecia to patients and regulatory agencies in other countries, Defendants failed to either alert Plaintiff, the public, and the scientific community in the United States or perform further investigation into the safety of docetaxel (TAXOTERE®) regarding the side effect of disfiguring permanent alopecia. Defendants failed to update the warnings for docetaxel (TAXOTERE®), and they failed to disclose the results of additional studies as Defendants learned new facts regarding the defects and risks of their product.

59. In particular, Defendants:

(a) failed to disclose their investigation and research from 2005, including but not limited to the results of the GEICAM 9805 study, and failed to further investigate, research, study, and define fully and adequately the safety profile of docetaxel (TAXOTERE®) in response to these studies;

- (b) failed to provide adequate warnings about the true safety risks associated with the use of docetaxel (TAXOTERE®);
- (c) failed to provide adequate warning regarding the pharmacokinetic and pharmacodynamic variability of docetaxel (TAXOTERE®) and its effects on the degree or severity of side effects related to permanent alopecia;
- (d) failed to disclose in the “Warnings” Section that permanent alopecia is a frequent side effect associated with the use of docetaxel (TAXOTERE®);
- (e) failed to advise prescribing physicians, such as Plaintiff’s physicians, to instruct patients that permanent alopecia was a side effect, much less a frequent side effect, linked to docetaxel (TAXOTERE®);
- (f) failed to provide adequate instructions on how to intervene and/or reduced the risk of permanent alopecia related to the use of docetaxel (TAXOTERE®);
- (g) failed to provide adequate warnings and information related to the increased risks of permanent alopecia in certain genome groups;
- (h) failed to provide adequate warnings regarding the increased risk of permanent alopecia with the use of docetaxel (TAXOTERE®) as compared to other products designed to treat the same conditions as docetaxel (TAXOTERE®); and
- (i) failed to include a **“BOXED WARNING”** related to permanent or persistent alopecia.

60. During the years since first marketing docetaxel (TAXOTERE®) in the U.S., Defendants modified the U.S. labeling and prescribing information for

1 docetaxel (TAXOTERE®) on multiple occasions. Defendants failed, however, to
2 include any warning whatsoever related to permanent alopecia despite
3 Defendants' awareness of the frequency and severity of this side effect.

4 61. Before applying for and obtaining approval of docetaxel
5 (TAXOTERE®), Defendants knew or should have known that consumption of
6 docetaxel (TAXOTERE®) was associated with and/or would cause disfiguring
7 side effects including disfiguring permanent alopecia.

8 62. Despite knowing that docetaxel (TAXOTERE®) was likely to result
9 in increased rates of alopecia and disfiguring permanent alopecia, Defendants
10 produced, marketed, and distributed docetaxel (TAXOTERE®) in the United
11 States.

12 63. Defendants failed to adequately conduct complete and proper testing
13 of docetaxel (TAXOTERE®) prior to filing their New Drug Application for
14 docetaxel (TAXOTERE®).

15 64. From the date Defendants received FDA approval to market
16 docetaxel (TAXOTERE®), Defendants made, distributed, marketed, and sold
17 docetaxel (TAXOTERE®) without adequate warning to Plaintiff or Plaintiff's
18 prescribing physicians that docetaxel (TAXOTERE®) was associated with
19 disfiguring permanent alopecia.

20 65. Defendants ignored the association between the use of docetaxel
21 (TAXOTERE®) and the risk of disfiguring permanent alopecia.

22 66. Defendants failed to disclose information that they possessed
23 regarding their failure to adequately test and study docetaxel (TAXOTERE®)
24 related to the side effect of disfiguring permanent alopecia. Plaintiff and her
25 healthcare providers could not have discovered Defendants' false representations
26 and failures to disclose information through the exercise of reasonable diligence.

67. As a result of the foregoing acts and omissions, Defendants caused Plaintiff to suffer serious and dangerous side effects, severe and personal injuries that are permanent and lasting in nature, and economic and non-economic damages, harms, and losses, including but not limited to: past and future medical expenses; psychological counseling and therapy expenses; past and future loss of earnings; past and future loss and impairment of earning capacity; permanent disfigurement including permanent alopecia; mental anguish; severe and debilitating emotional distress; increased risk of future harm; past, present, and future physical and mental pain, suffering, and discomfort; and past, present, and future loss and impairment of the quality and enjoyment of life.

**ESTOPPEL FROM PLEADING STATUTES OF LIMITATIONS OR
REPOSE**

68. Plaintiff incorporates by reference the averments of the preceding paragraphs of the Complaint as if fully set forth at length herein.

69. Plaintiff is within the applicable statutes of limitations for the claims presented herein because Plaintiff did not discover the defects and unreasonably dangerous condition of Defendants' docetaxel (TAXOTERE®) and the risks associated with its use in the form of disfiguring permanent alopecia, and could not reasonably have discovered the defects and unreasonably dangerous condition of Defendants' docetaxel (TAXOTERE®) and the risks associated with its use, due to the Defendants' failure to warn, suppression of important information about the risks of the drug, including but not limited to the true risk benefit profile, and the risk of disfiguring permanent alopecia and damages known by Defendants to result from the use of docetaxel (TAXOTERE®), and other acts and omissions.

70. In addition, Defendants are estopped from relying on any statutes of limitations or repose by virtue of their acts of fraudulent concealment, affirmative misrepresentations and omissions, which include Defendants' intentional

1 concealment from Plaintiff, Plaintiff's prescribing health care professionals and
2 the general consuming public that Defendants' docetaxel (TAXOTERE®) was
3 defective, unreasonably dangerous and carried with it the serious risk of
4 developing the injuries Plaintiff has suffered while aggressively and continually
5 marketing and promoting docetaxel (TAXOTERE®) as safe and effective. This
6 includes, but is not limited to, Defendants' failure to disclose and warn of the risk
7 of disfiguring permanent alopecia and injuries known by Defendants to result
8 from use of docetaxel (TAXOTERE®), for example, and not by way of limitation,
9 internal concern about reports and studies finding an increased risk of disfiguring
10 permanent alopecia; suppression of information about these risks and injuries
11 from physicians and patients, including Plaintiff; use of sales and marketing
12 documents and information that contained information contrary to the internally
13 held knowledge regarding the aforesaid risks and injuries; and overstatement of
14 the efficacy and safety of docetaxel (TAXOTERE®).

15 71. Defendants had a duty to disclose that docetaxel (TAXOTERE®)
16 was defective, unreasonably dangerous and that the use of Defendants' docetaxel
17 (TAXOTERE®) carried with it the serious risk of developing disfiguring
18 permanent alopecia as the Plaintiff has suffered. Defendants breached that duty.

19 72. Plaintiff, Plaintiff's prescribing health care professionals and the
20 general consuming public, had no knowledge of, and no reasonable way of
21 discovering, the defects found in Defendants' docetaxel (TAXOTERE®) or the
22 true risks associated with her use at the time she purchased and used Defendants'
23 docetaxel (TAXOTERE®).

24 73. Defendants did not notify, inform, or disclose to Plaintiff, Plaintiff's
25 prescribing health care professionals or the general consuming public that
26 Defendants' docetaxel (TAXOTERE®) was defective and that its use carried with
27

1 it the serious risk of developing the injuries Plaintiff has suffered and complained
2 of herein.

3 74. Because Defendants failed in their duty to notify Plaintiff, Plaintiff's
4 prescribing health care professionals and the general consuming public that their
5 docetaxel (TAXOTERE®) was defective and, further, actively attempted to
6 conceal this fact, Defendants should be estopped from asserting defenses based on
7 statutes of limitation or repose.

8 75. Accordingly, Plaintiff files this lawsuit within the applicable statutes
9 of limitations, Plaintiff could not by exercise of reasonable diligence have
10 discovered any wrongdoing, nor could have discovered the causes of her injuries
11 at an earlier time, and when Plaintiff's injuries were discovered, their causes were
12 not immediately known or knowable based on the lack of necessary information,
13 which was suppressed by the Defendants. Further, the relationship of Plaintiff's
14 injuries to docetaxel (TAXOTERE®) exposure through the Defendants' drug was
15 inherently difficult to discover, in part due to the Defendants' knowing
16 suppression of important safety information. Consequently, the discovery rule
17 should be applied to toll the running of the statutes of limitations until Plaintiff
18 discovered, or by the exercise of reasonable diligence should have discovered, that
19 Plaintiff may have a basis for an actionable claim.

20 **FIRST CLAIM FOR RELIEF**

21 **(Product Liability for Negligence – Against All Defendants)**

22 76. Plaintiff repeats, reiterates, and re-alleges all preceding paragraphs of
23 this Complaint inclusive, with the same force and effect as if fully set forth herein.

24 77. Defendants had a duty to exercise reasonable care in the designing,
25 researching, manufacturing, marketing, supplying, promoting, packaging, sale,
26 and/or distribution of docetaxel (TAXOTERE®) into the stream of commerce,
27

1 including a duty to assure that the product would not cause users to suffer
2 unreasonable, dangerous side effects.

3 78. Defendants failed to exercise reasonable care in the designing,
4 researching, manufacturing, marketing, supplying, promoting, packaging, sale,
5 testing, quality assurance, quality control, and/or distribution of docetaxel
6 (TAXOTERE®) into interstate commerce in that Defendants knew or should have
7 known that using docetaxel (TAXOTERE®) created a high risk of unreasonable,
8 disfiguring side effects, including personal injuries that are permanent and lasting
9 in nature such as disfiguring permanent alopecia, mental anguish, and diminished
10 enjoyment of life, economic loss, and loss of economic opportunity.

11 79. The negligence of Defendants, their agents, servants, and/or
12 employees, included but was not limited to the following acts and/or omissions:

- 13 (a) Manufacturing, producing, promoting, formulating, creating,
14 and/or designing docetaxel (TAXOTERE®) without
15 thoroughly testing it;
- 16 (b) Manufacturing, producing, promoting, formulating, creating,
17 and/or designing docetaxel (TAXOTERE®) without
18 adequately testing it;
- 19 (c) Not conducting sufficient testing programs to determine
20 whether or not docetaxel (TAXOTERE®) was safe for use in
21 that Defendants knew or should have known that docetaxel
22 (TAXOTERE®) was unsafe and unfit for use by reason of the
23 dangers to its users;
- 24 (d) Selling docetaxel (TAXOTERE®) without disclosing its
25 dangers and risks and/or making proper and sufficient tests to
26 determine the dangers and risks to its users;

- 1 (e) Negligently failing to adequately and correctly warn Plaintiff,
2 Plaintiffs' physicians, the public, and the medical and
3 healthcare profession of the dangers of docetaxel
4 (TAXOTERE®);
- 5 (f) Failing to provide adequate instructions regarding safety
6 precautions to be observed by users, handlers, and persons who
7 would reasonably and foreseeably come into contact with, and
8 more particularly, use, docetaxel (TAXOTERE®);
- 9 (g) Failing to test docetaxel (TAXOTERE®) and/or failing to
10 adequately, sufficiently, and properly test docetaxel
11 (TAXOTERE®);
- 12 (h) Negligently advertising and recommending the use of
13 docetaxel (TAXOTERE®) without sufficient knowledge as to
14 its dangerous propensities;
- 15 (i) Negligently representing that docetaxel (TAXOTERE®) was
16 safe for use for its intended purpose, when, in fact, it was
17 unsafe;
- 18 (j) Negligently and falsely representing that docetaxel
19 (TAXOTERE®) was superior to other commercially available
20 products designed to treat the same forms of cancer docetaxel
21 (TAXOTERE®) was designed to treat;
- 22 (k) Negligently designing docetaxel (TAXOTERE®) in a manner
23 that was dangerous to its users;
- 24 (l) Negligently manufacturing docetaxel (TAXOTERE®) in a
25 manner that was dangerous to its users;
- 26 (m) Negligently producing docetaxel (TAXOTERE®) in a manner
27 that was dangerous to its users;

- 1 (n) Negligently assembling docetaxel (TAXOTERE®) in a
2 manner that was dangerous to its users;
- 3 (o) Concealing information from Plaintiff, Plaintiff's physicians,
4 the public, and the FDA in knowing that docetaxel
5 (TAXOTERE®) was unsafe, dangerous, and/or non-
6 conforming with FDA regulations; and
- 7 (p) Improperly concealing from and/or misrepresenting
8 information to Plaintiff, Plaintiff's physicians, other healthcare
9 professionals, and/or the FDA concerning the severity of risks
10 and dangers of docetaxel (TAXOTERE®) compared to other
11 forms of treatment for breast cancer.

12 80. Defendants underreported, underestimated, and downplayed the
13 serious dangers and risk associated with docetaxel (TAXOTERE®).

14 81. Defendants negligently conveyed that the safety risks and/or dangers
15 of docetaxel (TAXOTERE®) were comparable with other forms of treatment for
16 the same conditions for which docetaxel (TAXOTERE®) was prescribed to treat.

17 82. Defendants were negligent in the designing, researching, supplying,
18 manufacturing, promoting, packaging, distributing, testing, advertising, warning,
19 marketing, and selling of docetaxel (TAXOTERE®) in that they:

- 20 (a) Failed to use due care in designing and manufacturing
21 docetaxel (TAXOTERE®) so as to avoid the aforementioned
22 risks to individuals when docetaxel (TAXOTERE®) was used
23 for the treatment of breast cancer;
- 24 (b) Failed to accompany their product with proper and/or accurate
25 warnings regarding all possible adverse side effects associated
26 with the use of docetaxel (TAXOTERE®);

- 1 (c) Failed to accompany their product with proper warnings
2 regarding all possible adverse side effects concerning the risks
3 and dangers associated with docetaxel (TAXOTERE®);
- 4 (d) Failed to accompany their product with accurate warnings
5 regarding the risks of all possible adverse side effects
6 concerning docetaxel (TAXOTERE®);
- 7 (e) Failed to warn Plaintiff and Plaintiff's physicians of the
8 severity and duration of such adverse effects, as the warnings
9 given did not accurately reflect the symptoms, or severity, of
10 the side effects;
- 11 (f) Failed to conduct adequate testing, including pre-clinical and
12 clinical testing and post-marketing surveillance, to determine
13 the safety, dangers, and risks associated with docetaxel
14 (TAXOTERE®).
- 15 (g) Failed to warn Plaintiff and Plaintiff's physicians before
16 actively encouraging the sale of docetaxel (TAXOTERE®),
17 either directly or indirectly, orally or in writing, about the need
18 for more comprehensive and regular medical monitoring than
19 usual to ensure early discovery of potentially serious side
20 effects; and
- 21 (h) Were otherwise careless and/or negligent.

22 83. Despite the fact that Defendants knew or should have known that
23 docetaxel (TAXOTERE®) caused unreasonably dangerous side effects,
24 Defendants continued and continue to market, manufacture, distribute, and/or sell
25 docetaxel (TAXOTERE®) to consumers, including Plaintiff.

26 84. Defendants negligently and improperly failed to perform sufficient
27 tests, forcing Plaintiff, Plaintiff's physicians, and/or hospitals to rely on safety

1 information that did not accurately represent the risks and benefits associated with
2 the use of docetaxel (TAXOTERE®) as compared to other products already
3 commercially available to treat the same types of cancer docetaxel
4 (TAXOTERE®) was designed to treat.

5 85. Defendants knew or should have known that consumers such as
6 Plaintiff would use their product and would foreseeably suffer injury as a result of
7 Defendants' failure to exercise reasonable care, as set forth above.

8 86. Defendants' negligence was the proximate cause of Plaintiff's
9 injuries, harms, damages, and losses.

10 87. As a direct and proximate result of the use of docetaxel
11 (TAXOTERE®), Plaintiff experienced disfiguring permanent alopecia.

12 88. As a result of the foregoing acts and omissions, Defendants caused
13 Plaintiff to suffer serious and dangerous side effects, severe and personal injuries
14 that are permanent and lasting in nature, and economic and non-economic
15 damages, harms, and losses, including but not limited to: past and future medical
16 expenses; psychological counseling and therapy expenses; past and future loss of
17 earnings; past and future loss and impairment of earning capacity; permanent
18 disfigurement including permanent alopecia; mental anguish; severe and
19 debilitating emotional distress; increased risk of future harm; past, present, and
20 future physical and mental pain, suffering, and discomfort; and past, present, and
21 future loss and impairment of the quality and enjoyment of life.

22 **SECOND CLAIM FOR RELIEF**

23 **(Strict Products Liability – Design and Manufacturing Defects –** 24 **Against All Defendants)**

25 89. Plaintiff repeats, reiterates, and re-alleges all preceding paragraphs of
26 this Complaint inclusive, with the same force and effect as if fully set forth herein.

1 90. At all times relevant, Defendants designed, researched,
2 manufactured, tested, advertised, promoted, marketed, sold, distributed, and/or
3 have recently acquired the entities that have designed, researched, manufactured,
4 tested, advertised, promoted, marketed, sold, and distributed docetaxel
5 (TAXOTERE®) as hereinabove described that was used by Plaintiff.

6 91. Docetaxel (TAXOTERE®) was expected to and did reach the usual
7 consumers, handlers, and persons coming into contact with said product without
8 substantial change in the condition in which it was produced, manufactured, sold,
9 distributed, and marketed by Defendants.

10 92. At those times, docetaxel (TAXOTERE®) was in an unsafe,
11 defective, and inherently dangerous condition, which was dangerous to users, and
12 in particular, Plaintiff.

13 93. The docetaxel (TAXOTERE®) designed, researched, manufactured,
14 tested, advertised, promoted, marketed, sold, and distributed by Defendants was
15 defective in design or formulation in that, when it left the hands of the
16 manufacturer and/or suppliers, the foreseeable risks exceeded the benefits
17 associated with the design or formulation of docetaxel (TAXOTERE®).

18 94. The docetaxel (TAXOTERE®) designed, researched, manufactured,
19 tested, advertised, promoted, marketed, sold, and distributed by Defendants was
20 defective in design and/or formulation, in that, when it left the hands of
21 Defendants, manufacturers, and/or suppliers, it was unreasonably dangerous, and
22 it was more dangerous and posed risk greater than an ordinary consumer would
23 expect.

24 95. At all times relevant, docetaxel (TAXOTERE®) was in a defective
25 condition and unsafe, and Defendants knew or had reason to know that docetaxel
26 (TAXOTERE®) was defective and unsafe, especially when used in the form and
27 manner as provided by Defendants.

1 104. Plaintiff and Plaintiff's physicians could not, by the exercise of
2 reasonable care, have discovered docetaxel (TAXOTERE®)'s defects mentioned
3 herein and perceived its danger.

4 105. The docetaxel (TAXOTERE®) designed, researched, manufactured,
5 tested, advertised, promoted, marketed, sold, and distributed by Defendants was
6 defective due to inadequate warnings or instructions, as Defendants knew or
7 should have known that the product created a risk of serious and dangerous side
8 effects including disfigurement as well as other severe and personal injuries that
9 are permanent and lasting in nature, and Defendants failed to adequately warn of
10 these risks.

11 106. The docetaxel (TAXOTERE®) designed, researched, manufactured,
12 tested, advertised, promoted, marketed, sold, and distributed by Defendants was
13 defective due to inadequate warnings and/or inadequate testing.

14 107. The docetaxel (TAXOTERE®) designed, researched, manufactured,
15 tested, advertised, promoted, marketed, sold, and distributed by Defendants was
16 defective due to inadequate post-marketing surveillance and/or warnings because,
17 after Defendants knew or should have known of the risks of serious side effects,
18 including disfigurement, as well as other severe and permanent health
19 consequences from docetaxel (TAXOTERE®), they failed to provide adequate
20 warnings to users or consumers of the product, and they continued to improperly
21 advertise, market, and/or promote docetaxel (TAXOTERE®).

22 108. By reason of the foregoing, Defendants are strictly liable to Plaintiff
23 for the manufacturing, marketing, promoting, distribution, and selling of docetaxel
24 (TAXOTERE®), a defective product.

25 109. Defendants' defective design, manufacturing defect, and inadequate
26 warnings of docetaxel (TAXOTERE®) were acts that amount to willful, wanton,
27 and/or reckless conduct by Defendants.

110. The defects in Defendants' drug docetaxel (TAXOTERE®) were a producing cause and a substantial factor in causing Plaintiff's injuries.

111. As a result of the foregoing acts and omissions, Defendants caused Plaintiff to suffer serious and dangerous side effects, severe and personal injuries that are permanent and lasting in nature, and economic and non-economic damages, harms, and losses, including but not limited to: past and future medical expenses; psychological counseling and therapy expenses; past and future loss of earnings; past and future loss and impairment of earning capacity; permanent disfigurement including permanent alopecia; mental anguish; severe and debilitating emotional distress; increased risk of future harm; past, present, and future physical and mental pain, suffering, and discomfort; and past, present, and future loss and impairment of the quality and enjoyment of life.

THIRD CLAIM FOR RELIEF

(Strict Products Liability – Failure to Warn – Against All Defendants)

112. Plaintiff repeats, reiterates, and re-alleges all preceding paragraphs of this Complaint inclusive, with the same force and effect as if fully set forth herein.

113. The docetaxel (TAXOTERE®) designed, formulated, produced, manufactured, sold, marketed, distributed, supplied and/or placed into the stream of commerce by Defendants was defective in that it failed to include adequate warnings regarding all adverse side effects associated with the use of docetaxel (TAXOTERE®). The warnings given by Defendants did not sufficiently and/or accurately reflect the symptoms, type, scope, severity, or duration of the side effects and, in particular, the risks of disfiguring permanent alopecia. As the holder for the RLD of brand-name TAXOTERE®, the Sanofi Defendants supplied the labeling for Winthrop U.S.'s generic version of TAXOTERE®. This

1 labeling was defective because it failed to adequately warn of the risk of
2 disfiguring permanent alopecia.

3 114. Defendants failed to provide adequate warnings to physicians and
4 users, including Plaintiff's physicians and Plaintiff, of the increased risk of
5 disfiguring permanent alopecia associated with docetaxel (TAXOTERE®), and
6 Defendants aggressively and fraudulently promoted the product to physicians.

7 115. As a direct and proximate result of Defendants' failure to warn of the
8 potentially severe adverse effects of docetaxel (TAXOTERE®), Plaintiff suffered
9 disfiguring permanent alopecia and other conditions.

10 116. As a result of the foregoing acts and omissions, Defendants caused
11 Plaintiff to suffer serious and dangerous side effects, severe and personal injuries
12 that are permanent and lasting in nature, and economic and non-economic
13 damages, harms, and losses, including but not limited to: past and future medical
14 expenses; psychological counseling and therapy expenses; past and future loss of
15 earnings; past and future loss and impairment of earning capacity; permanent
16 disfigurement including permanent alopecia; mental anguish; severe and
17 debilitating emotional distress; increased risk of future harm; past, present, and
18 future physical and mental pain, suffering, and discomfort; and past, present, and
19 future loss and impairment of the quality and enjoyment of life.

20 **FOURTH CLAIM FOR RELIEF**

21 **(Breach of Express Warranty – Against All Defendants)**

22 117. Plaintiff repeats, reiterates, and re-alleges all preceding paragraphs of
23 this Complaint inclusive, with the same force and effect as if fully set forth herein.

24 118. Defendants expressly warranted that Docetaxel (TAXOTERE®) was
25 safe and well accepted by users.

26 119. Docetaxel (TAXOTERE®) does not conform to these express
27 representations, because Docetaxel (TAXOTERE®) is not safe and has numerous

1 serious side effects, many of which were not accurately warned about by
2 Defendants.

3 120. As a direct and proximate result of the breach of these warranties,
4 Plaintiff suffered and will continue to suffer severe and permanent personal
5 injuries, disfigurement, harms, and losses.

6 121. Plaintiff relied on Defendants' express warranties.

7 122. Members of the medical community, including physicians and other
8 healthcare professionals, relied upon the representations and warranties of
9 Defendants for use of Docetaxel (TAXOTERE®) in recommending, prescribing,
10 and/or dispensing Docetaxel (TAXOTERE®). Defendants breached the aforesaid
11 express warranties, as their drug Docetaxel (TAXOTERE®) was and is defective.

12 123. Defendants expressly represented to Plaintiff, Plaintiff's physicians,
13 and/or healthcare providers that docetaxel (TAXOTERE®) was safe and fit for
14 use for the purposes intended, that it was of merchantable quality, that it did not
15 produce any dangerous side effects in excess of those risks associated with other
16 forms of treatment for cancer, that the side effects it did produce were accurately
17 reflected in the warnings, and that it was adequately tested and fit for its intended
18 use.

19 124. Defendants knew or should have known that, in fact, their
20 representations and warranties were false, misleading, and untrue in that docetaxel
21 (TAXOTERE®) was not safe and fit for the use intended, and, in fact, docetaxel
22 (TAXOTERE®) produced serious injuries to the users that were not accurately
23 identified and represented by Defendants.

24 125. As a result of the foregoing acts and omissions, Defendants caused
25 Plaintiff to suffer serious and dangerous side effects, severe and personal injuries
26 that are permanent and lasting in nature, and economic and non-economic
27 damages, harms, and losses, including but not limited to: past and future medical

1 expenses; psychological counseling and therapy expenses; past and future loss of
2 earnings; past and future loss and impairment of earning capacity; permanent
3 disfigurement including permanent alopecia; mental anguish; severe and
4 debilitating emotional distress; increased risk of future harm; past, present, and
5 future physical and mental pain, suffering, and discomfort; and past, present, and
6 future loss and impairment of the quality and enjoyment of life.

7 **FIFTH CLAIM FOR RELIEF**

8 **(Breach of Implied Warranty – Against All Defendants)**

9 126. Plaintiff repeats, reiterates, and re-alleges all preceding paragraphs of
10 this Complaint inclusive, with the same force and effect as if fully set forth herein.

11 127. At all times relevant, Defendants manufactured, compounded,
12 portrayed, distributed, recommended, merchandized, advertised, promoted, and
13 sold docetaxel (TAXOTERE®) and/or have recently acquired the entities that
14 have manufactured, compounded, portrayed, distributed, recommended,
15 merchandized, advertised, promoted, and sold docetaxel (TAXOTERE®) for the
16 treatment of various forms of cancer.

17 128. At the time Defendants marketed, sold, and distributed docetaxel
18 (TAXOTERE®) for use by Plaintiff, Defendants knew of the use for which
19 docetaxel (TAXOTERE®) was intended and impliedly warranted the product to
20 be of merchantable quality and safe and fit for such use.

21 129. Defendants impliedly represented and warranted to the users of
22 docetaxel (TAXOTERE®) and their physicians, and/or healthcare providers that
23 docetaxel (TAXOTERE®) was safe and of merchantable quality and fit for the
24 ordinary purpose for which it was to be used.

25 130. Defendants' aforementioned representations and warranties were
26 false, misleading, and inaccurate in that docetaxel (TAXOTERE®) was unsafe,
27 unreasonably dangerous, improper, not of merchantable quality, and defective.

SIXTH CLAIM FOR RELIEF

(Fraudulent Misrepresentation – Against All Defendants)

137. Plaintiff repeats, reiterates, and re-alleges all preceding paragraphs of this Complaint inclusive, with the same force and effect as if fully set forth herein.

138. Defendants falsely and fraudulently represented to Plaintiff, Plaintiff's physicians, the medical and healthcare community, and the public in general that docetaxel (TAXOTERE®) had been tested and was found to be safe and effective for the treatment of certain forms of cancer.

139. When warning of safety and risks of docetaxel (TAXOTERE®), Defendants fraudulently represented to Plaintiff, Plaintiff's physicians, the medical and healthcare community, and the public in general that docetaxel (TAXOTERE®) had been tested and was found to be safe and/or effective for its indicated use.

140. Defendants concealed their knowledge of docetaxel's (TAXOTERE®'s) defects from Plaintiff, Plaintiff's physicians, and the public in general and/or the medical community specifically.

141. Defendants concealed their knowledge of the defects in their products from Plaintiff, Plaintiff's physicians, hospitals, pharmacists, and the public in general.

142. Defendants made these false representations with the intent of defrauding and deceiving Plaintiff, Plaintiff's physicians, the public in general, and the medical and healthcare community in particular, and were made with the intent of inducing Plaintiff, Plaintiff's physicians, the public in general, and the medical community in particular, to recommend, dispense, and/or purchase docetaxel (TAXOTERE®) for use in the treatments of various forms of cancer, including but not limited to breast cancer, all of which evidenced a callous,

reckless, willful, wanton, and depraved indifference to the health, safety, and welfare of Plaintiff.

143. Defendants made these false representations with the intent of defrauding and deceiving Plaintiff, Plaintiff's physicians, as well as the public in general, and the medical and healthcare community in particular, and were made with the intent of inducing the public in general, and the medical community in particular, to recommend, dispense, and/or purchase docetaxel (TAXOTERE®) for use in the treatments of various forms of cancer, including but not limited to breast cancer.

144. When Defendants made these representations, Defendants knew those representations were false, and Defendants willfully, wantonly, and recklessly disregarded whether the representations were true.

145. At the time Defendants made the aforesaid representations, and, at the time Plaintiff used docetaxel (TAXOTERE®), Plaintiff and Plaintiff's physicians were unaware of the falsity of Defendants' representations, and Plaintiff and Plaintiff's physicians reasonably believed them to be true.

146. In reliance upon Defendants' representations, Plaintiff and Plaintiff's physicians were induced to and did use and prescribe docetaxel (TAXOTERE®), which caused Plaintiff to sustain severe, permanent, and disfiguring personal injuries.

147. Defendants knew and were aware or should have been aware that docetaxel (TAXOTERE®) had not been sufficiently tested, was defective in nature, and/or that it lacked adequate and/or sufficient warnings.

148. Defendants knew or should have known that docetaxel (TAXOTERE®) had a potential to, could, and would cause severe and grievous injury to the users of docetaxel (TAXOTERE®) and that docetaxel

(TAXOTERE®) was inherently dangerous in a manner that exceeded any purported, inaccurate, and/or down-played warnings.

149. Defendants brought docetaxel (TAXOTERE®) to the market and acted fraudulently, wantonly, and maliciously to the detriment of Plaintiff.

150. As a result of the foregoing acts and omissions, Defendants caused Plaintiff to suffer serious and dangerous side effects, severe and personal injuries that are permanent and lasting in nature, and economic and non-economic damages, harms, and losses, including but not limited to: past and future medical expenses; psychological counseling and therapy expenses; past and future loss of earnings; past and future loss and impairment of earning capacity; permanent disfigurement including permanent alopecia; mental anguish; severe and debilitating emotional distress; increased risk of future harm; past, present, and future physical and mental pain, suffering, and discomfort; and past, present, and future loss and impairment of the quality and enjoyment of life.

SEVENTH CLAIM FOR RELIEF

(Fraudulent Concealment – Against All Defendants)

151. Plaintiff repeats, reiterates, and re-alleges all preceding paragraphs of this Complaint inclusive, with the same force and effect as if fully set forth herein.

152. At all times during the course of dealing between Defendants and Plaintiff and Plaintiff's healthcare providers, Defendants misrepresented the design characteristics and safety of docetaxel (TAXOTERE®) for its intended use.

153. Defendants knew or were reckless in not knowing that its representations were false.

154. In representations made to Plaintiff and Plaintiff's healthcare providers, Defendants fraudulently concealed and intentionally omitted the following material information:

- 1 (a) that docetaxel (TAXOTERE®) was not as safe as other forms
2 of treatment for which docetaxel (TAXOTERE®) was
3 marketed and sold to cancer patients;
- 4 (b) that the risks of adverse events with docetaxel (TAXOTERE®)
5 were higher than those with other forms of treatment for which
6 docetaxel (TAXOTERE®) was marketed and sold to cancer
7 patients;
- 8 (c) that the risks of adverse events with docetaxel (TAXOTERE®)
9 were not adequately tested and/or known by Defendants;
- 10 (d) that Defendants were aware of dangers in docetaxel
11 (TAXOTERE®), in addition to and above and beyond those
12 associated with other forms of treatment for cancer patients;
- 13 (e) that docetaxel (TAXOTERE®) was defective in that it caused
14 dangerous side effects as well as other severe and permanent
15 health consequences in a much more and significant rate than
16 other forms of treatment for cancer patients;
- 17 (f) that docetaxel (TAXOTERE®) was manufactured negligently;
- 18 (g) that docetaxel (TAXOTERE®) was manufactured defectively;
- 19 (h) that docetaxel (TAXOTERE®) was manufactured improperly;
- 20 (i) that docetaxel (TAXOTERE®) was designed negligently;
- 21 (j) that Docetaxel (TAXOTERE®) was designed defectively; and
- 22 (k) that docetaxel (TAXOTERE®) was designed improperly.

23 155. Defendants had a duty to disclose to Plaintiff, Plaintiff's physicians,
24 hospitals, and/or healthcare providers the defective nature of docetaxel
25 (TAXOTERE®), including but not limited to the heightened risks of disfiguring
26 permanent alopecia.

1 156. Defendants had sole access to material facts concerning the defective
2 nature of docetaxel (TAXOTERE®) and its propensity to cause serious and
3 dangerous side effects, and therefore cause damage to persons who used docetaxel
4 (TAXOTERE®), including Plaintiff, in particular.

5 157. Defendants' concealment and omissions of material facts concerning
6 the safety of docetaxel (TAXOTERE®) was made purposefully, willfully,
7 wantonly, and/or recklessly to mislead Plaintiff, Plaintiff's physicians, hospitals,
8 and healthcare providers into reliance on the continued use of Docetaxel
9 (TAXOTERE®) and to cause them to purchase, prescribe, and/or dispense
10 docetaxel (TAXOTERE®) and/or use docetaxel (TAXOTERE®).

11 158. Defendants knew that Plaintiff, Plaintiff's physicians, hospitals,
12 and/or healthcare providers had no way to determine the truth behind Defendants'
13 concealment and omissions, including the material omissions of facts surrounding
14 docetaxel (TAXOTERE®) set forth herein.

15 159. Plaintiff, Plaintiff's physicians, healthcare providers, and/or hospitals
16 reasonably relied on information revealed by Defendants that negligently,
17 fraudulently, and/or purposefully did not include facts that were concealed and/or
18 omitted by Defendants.

19 160. As a result of the foregoing acts and omissions, Defendants caused
20 Plaintiff to suffer serious and dangerous side effects, severe and personal injuries
21 that are permanent and lasting in nature, and economic and non-economic
22 damages, harms, and losses, including but not limited to: past and future medical
23 expenses; psychological counseling and therapy expenses; past and future loss of
24 earnings; past and future loss and impairment of earning capacity; permanent
25 disfigurement including permanent alopecia; mental anguish; severe and
26 debilitating emotional distress; increased risk of future harm; past, present, and

1 future physical and mental pain, suffering, and discomfort; and past, present, and
2 future loss and impairment of the quality and enjoyment of life.

3 **EIGHTH CLAIM FOR RELIEF**

4 **(Negligent Misrepresentation – Against All Defendants)**

5 161. Plaintiff repeats, reiterates, and re-alleges all preceding paragraphs of
6 this Complaint inclusive, with the same force and effect as if fully set forth herein.

7 162. Defendants had a duty to represent to Plaintiff, Plaintiff's physicians,
8 the medical and healthcare community, and the public in general that docetaxel
9 (TAXOTERE®) had been tested and found to be safe and effective for the
10 treatment of various forms of cancer.

11 163. When warning of safety and risks of docetaxel (TAXOTERE®),
12 Defendants negligently represented to Plaintiff, Plaintiff's physicians, the medical
13 and healthcare community, and the public in general that docetaxel
14 (TAXOTERE®) had been tested and was found to be safe and/or effective for its
15 indicated use.

16 164. Defendants concealed their knowledge of docetaxel's
17 (TAXOTERE®'s) defects from Plaintiff, Plaintiff's physicians, and the public in
18 general and/or the medical community specifically.

19 165. Defendants concealed their knowledge of the defects in their products
20 from Plaintiff, Plaintiff's physicians, hospitals, pharmacists, and the public in
21 general.

22 166. Defendants misrepresented the novel nature of their product in order
23 to gain a market advantage resulting in billions of dollars in revenues at the
24 expense of vulnerable cancer victims such as Plaintiff.

25 167. Defendants made these misrepresentations with the intent of
26 defrauding and deceiving Plaintiff, Plaintiff's physicians, the public in general,
27 and the medical and healthcare community in particular, and were made with the

1 intent of inducing Plaintiff, Plaintiff's physicians, the public in general, and the
2 medical community in particular, to recommend, dispense, and/or purchase
3 docetaxel (TAXOTERE®) for use in the treatments of various forms of cancer,
4 including but not limited to breast cancer.

5 168. Defendants failed to exercise ordinary and reasonable care in their
6 representations of docetaxel (TAXOTERE®) while involved in its manufacture,
7 sale, testing, quality assurance, quality control, and/or distribution into interstate
8 commerce, and Defendants negligently misrepresented docetaxel's
9 (TAXOTERE®'s) high risk of unreasonable, dangerous side effects.

10 169. Defendants breached their duty in misrepresenting docetaxel's
11 (TAXOTERE®'s) serious side effects to Plaintiff, Plaintiff's physicians, the
12 medical and healthcare community, the FDA, and the public in general.

13 170. Plaintiff and Plaintiff's physicians reasonably relied on Defendants to
14 fulfill their obligations to disclose all facts within their knowledge regarding the
15 serious side effects of docetaxel (TAXOTERE®).

16 171. As a result of the foregoing acts and omissions, Defendants caused
17 Plaintiff to suffer serious and dangerous side effects, severe and personal injuries
18 that are permanent and lasting in nature, and economic and non-economic
19 damages, harms, and losses, including but not limited to: past and future medical
20 expenses; psychological counseling and therapy expenses; past and future loss of
21 earnings; past and future loss and impairment of earning capacity; permanent
22 disfigurement including permanent alopecia; mental anguish; severe and
23 debilitating emotional distress; increased risk of future harm; past, present, and
24 future physical and mental pain, suffering, and discomfort; and past, present, and
25 future loss and impairment of the quality and enjoyment of life.

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NINTH CLAIM FOR RELIEF

(Strict Product Liability for Misrepresentation – Against All Defendants)

172. Plaintiff repeats, reiterates, and re-alleges all preceding paragraphs of this Complaint inclusive, with the same force and effect as if fully set forth herein.

173. Defendants sold the docetaxel (TAXOTERE®) that Plaintiff's physician prescribed for Plaintiff and that Plaintiff used.

174. Defendants were engaged in the business of selling the docetaxel (TAXOTERE®) for resale, use, or consumption.

175. Defendants misrepresented facts as set forth herein concerning the character or quality of the docetaxel (TAXOTERE®) that would be material to potential prescribers and purchasers or users of the product.

176. Defendants' misrepresentations were made to potential prescribers and/or purchasers or users as members of the public at large.

177. As a purchaser or user, Plaintiff reasonably relied on the misrepresentation.

178. Plaintiff was a person who would reasonably be expected to use, consume, or be affected by the docetaxel (TAXOTERE®).

179. As a result of the foregoing acts and omissions, Defendants caused Plaintiff to suffer serious and dangerous side effects, severe and personal injuries that are permanent and lasting in nature, and economic and non-economic damages, harms, and losses, including but not limited to: past and future medical expenses; psychological counseling and therapy expenses; past and future loss of earnings; past and future loss and impairment of earning capacity; permanent disfigurement including permanent alopecia; mental anguish; severe and debilitating emotional distress; increased risk of future harm; past, present, and future physical and mental pain, suffering, and discomfort; and past, present, and future loss and impairment of the quality and enjoyment of life.

TENTH CLAIM FOR RELIEF

(Fraud and Deceit – Against All Defendants)

180. Plaintiff repeats, reiterates, and re-alleges all preceding paragraphs of this Complaint inclusive, with the same force and effect as if fully set forth herein.

181. Defendants committed fraud by omission in applying for and gaining patent protection for docetaxel (TAXOTERE®) resulting in increased sales and market penetration. This increased market penetration was the proximal cause of Plaintiff's exposure to the side effects of docetaxel (TAXOTERE®).

182. Defendants fraudulently claimed superior efficacy over other products designed to treat the same conditions for which docetaxel (TAXOTERE®) was designed to treat. These fraudulent representations were the proximal cause of Plaintiff's exposure to the side effects of docetaxel (TAXOTERE®).

183. As a result of Defendants' research and testing, or lack thereof, Defendants intentionally distributed false information, including but not limited to assuring Plaintiff, Plaintiff's physicians, hospitals, healthcare professionals, and/or the public that docetaxel (TAXOTERE®) was safe and effective for use in the treatment of various forms of cancer, including breast cancer.

184. As a result of Defendants' research and testing, or lack thereof, Defendants intentionally omitted certain results of testing and or research to Plaintiff, Plaintiff's physicians, healthcare professionals, and/or the public.

185. Defendants had a duty when disseminating information to Plaintiff, Plaintiff's physicians, and the public to disseminate truthful information.

186. Defendants had a duty when disseminating information to Plaintiff, Plaintiff's physicians, and the public not to deceive Plaintiff, Plaintiff's physicians, and/or the public.

1 187. The information Defendants distributed to Plaintiff, Plaintiff's
2 physicians, and the public, including but not limited to reports, press releases,
3 advertising campaigns, and other forms of media contained material
4 representations of fact and/or omissions.

5 188. The information Defendants distributed to Plaintiff, Plaintiff's
6 physicians, and the public intentionally included false representations that
7 Defendants' drug docetaxel (TAXOTERE®) was safe and effective for the
8 treatment of various forms of cancer, including breast cancer.

9 189. The information Defendants distributed to Plaintiff, Plaintiff's
10 physicians, and the public intentionally included false representations that
11 Defendants' drug docetaxel (TAXOTERE®) carried the same risks, hazards,
12 and/or dangers as other forms of treatment for the same conditions for which
13 docetaxel (TAXOTERE®) was designed to treat.

14 190. The information Defendants distributed to Plaintiff, Plaintiff's
15 physicians, and the public intentionally included false representations that
16 docetaxel (TAXOTERE®) was not injurious to the health and/or safety of its
17 intended users.

18 191. The information Defendants distributed to Plaintiff, Plaintiff's
19 physicians, and the public intentionally included false representations that
20 docetaxel (TAXOTERE®) was no more injurious to the health and/or safety of its
21 intended users as other forms of cancer treatments for which docetaxel
22 (TAXOTERE®) was designed to treat.

23 192. These representations by Defendants were all false and misleading.

24 193. Defendants intentionally suppressed, ignored, and disregarded test
25 results not favorable to Defendants and that demonstrated that docetaxel
26 (TAXOTERE®) was not safe as a means of treatment for certain types of cancer
27 for which docetaxel (TAXOTERE®) was designed to treat.

1 194. Defendants intentionally made material misrepresentations to
2 Plaintiff, Plaintiff's physicians, and the public, including the medical profession,
3 regarding the safety of docetaxel (TAXOTERE®), specifically but not limited to
4 docetaxel (TAXOTERE®) not having dangerous and serious health and/or safety
5 concerns.

6 195. Defendants intentionally made material misrepresentations to
7 Plaintiff, Plaintiff's physicians, and the public in general, including the medical
8 profession, regarding the safety of docetaxel (TAXOTERE®), specifically but not
9 limited to docetaxel (TAXOTERE®) being as safe as other products designed to
10 treat the same conditions docetaxel (TAXOTERE®) was designed to treat.

11 196. It was Defendants' intent and purpose in making these false
12 representations to deceive and defraud Plaintiff, Plaintiff's physicians, and/or the
13 public and to gain the confidence of Plaintiff, Plaintiff's physicians, the public,
14 and/or healthcare professionals to falsely ensure the quality and fitness for use of
15 docetaxel (TAXOTERE®) and induce Plaintiff, Plaintiff's physicians, and the
16 public, including the medical profession, to purchase, request, dispense, prescribe,
17 recommend, and/or continue to use docetaxel (TAXOTERE®).

18 197. Defendants made the aforementioned false claims and false
19 representations with the intent of convincing Plaintiff, Plaintiff's physicians, the
20 public, and/or healthcare professionals that docetaxel (TAXOTERE®) was fit and
21 safe for use as treatment for certain types of cancer, including breast cancer.

22 198. Defendants made the aforementioned false claims and false
23 representations with the intent of convincing Plaintiff, Plaintiff's physicians, the
24 public, and/or healthcare professionals that docetaxel (TAXOTERE®) was fit and
25 safe for use as treatment of certain forms of cancer and did not pose risks,
26 dangers, or hazards above and beyond those identified and/or associated with
27

1 other forms of treatment for which docetaxel (TAXOTERE®) was designed to
2 treat.

3 199. Defendants made false claims and false representations in its
4 documents submitted to Plaintiff, Plaintiff's physicians, the public, and healthcare
5 professionals that docetaxel (TAXOTERE®) did not present risks related to
6 disfigurement secondary to permanent alopecia.

7 200. Defendants made false claims and false representations in its
8 documents submitted to Plaintiff, Plaintiff's physicians, the public, and healthcare
9 professionals that docetaxel (TAXOTERE®) did not present health and/or safety
10 risks greater than other forms of treatment for the same conditions docetaxel
11 (TAXOTERE®) was designed to treat.

12 201. Defendants made these and other representations with a pretense of
13 actual knowledge when Defendants had no knowledge of the truth or falsity of
14 these representations, and Defendants made these representations recklessly and
15 without regard to the actual facts.

16 202. Defendants made these and other representations with the intention of
17 deceiving and defrauding Plaintiff and Plaintiff's respective healthcare
18 professionals.

19 203. Defendants made these and other representations in order to induce
20 Plaintiff and Plaintiff's respective healthcare professionals to rely upon the
21 misrepresentations.

22 204. Defendants' false misrepresentations caused Plaintiff and/or
23 Plaintiff's healthcare professionals to purchase, use, rely on, request, dispense,
24 recommend, and/or prescribe docetaxel (TAXOTERE®).

25 205. Defendants recklessly and intentionally falsely represented the
26 dangerous and serious health and/or safety concerns of docetaxel (TAXOTERE®)
27 to the public at large, and Plaintiff and Plaintiff's physicians in particular, for the

1 purpose of influencing the marketing of a product Defendants knew was
2 dangerous and defective and/or not as safe as other alternatives, including other
3 forms of treatment for cancer.

4 206. Defendants willfully and intentionally failed to disclose, concealed,
5 and/or suppressed the material facts regarding the dangerous and serious health
6 and/or safety concerns related to docetaxel (TAXOTERE®).

7 207. Defendants willfully and intentionally failed to disclose the truth and
8 material facts related to docetaxel (TAXOTERE®) and made false representations
9 with the purpose and design of deceiving and lulling Plaintiff and Plaintiff's
10 respective healthcare professionals into a sense of security so that Plaintiff and
11 Plaintiff's healthcare professionals would rely on Defendants' representations to
12 purchase, use, dispense, prescribe, and/or recommend docetaxel (TAXOTERE®).

13 208. Defendants, through their public relations efforts, which included but
14 were not limited to public statements and press releases, knew or should have
15 known that the public, including Plaintiff and Plaintiff's respective healthcare
16 professionals, would rely upon the information being disseminated.

17 209. Plaintiff and/or Plaintiff's respective healthcare professionals did in
18 fact rely on and believe Defendants' false representations to be true at the time
19 they were made, and they relied upon Defendants' false representations and
20 superior knowledge of how docetaxel (TAXOTERE®) would treat certain forms
21 of cancer for which docetaxel (TAXOTERE®) was designed to treat.

22 210. At the time Defendants' false representations were made, Plaintiff
23 and/or Plaintiff's respective healthcare providers did not know the truth and were
24 not with reasonable diligence able to discover the truth with regard to the
25 dangerous and serious health and/or safety concerns of docetaxel
26 (TAXOTERE®).

211. Plaintiff and her healthcare providers did not discover the true facts with respect to Defendants' false representations and the dangerous and serious health and/or safety concerns of docetaxel (TAXOTERE®), and Plaintiff and her healthcare providers with reasonable diligence could not have discovered the true facts.

212. Had Plaintiff and her healthcare providers known the true facts with respect to the dangerous and serious health and/or safety concerns of docetaxel (TAXOTERE®), Plaintiff would not have purchased, used, and/or relied on Defendants' drug docetaxel (TAXOTERE®).

213. Defendants' aforementioned conduct constitutes fraud and deceit, and it was committed and/or perpetrated willfully, wantonly, and/or purposefully on Plaintiff.

214. As a result of the foregoing acts and omissions, Defendants caused Plaintiff to suffer serious and dangerous side effects, severe and personal injuries that are permanent and lasting in nature, and economic and non-economic damages, harms, and losses, including but not limited to: past and future medical expenses; psychological counseling and therapy expenses; past and future loss of earnings; past and future loss and impairment of earning capacity; permanent disfigurement including permanent alopecia; mental anguish; severe and debilitating emotional distress; increased risk of future harm; past, present, and future physical and mental pain, suffering, and discomfort; and past, present, and future loss and impairment of the quality and enjoyment of life.

ELEVENTH CLAIM FOR RELIEF

(Extreme and Outrageous Conduct / Intentional Infliction of Emotional Distress – Against All Defendants)

215. Plaintiff repeats, reiterates, and re-alleges all preceding paragraphs of this Complaint inclusive, with the same force and effect as if fully set forth herein.

1 216. Defendants' conduct, as set forth above, was extreme and outrageous.

2 217. Defendants' actions were done recklessly or with the intent of
3 causing Plaintiff severe emotional distress; and

4 218. Defendants' conduct caused Plaintiff severe emotional distress.

5 219. As a result of the foregoing acts and omissions, Defendants caused
6 Plaintiff to suffer serious and dangerous side effects, severe and personal injuries
7 that are permanent and lasting in nature, and economic and non-economic
8 damages, harms, and losses, including but not limited to: past and future medical
9 expenses; psychological counseling and therapy expenses; past and future loss of
10 earnings; past and future loss and impairment of earning capacity; permanent
11 disfigurement including permanent alopecia; mental anguish; severe and
12 debilitating emotional distress; increased risk of future harm; past, present, and
13 future physical and mental pain, suffering, and discomfort; and past, present, and
14 future loss and impairment of the quality and enjoyment of life.

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PRAYER FOR RELIEF

WHEREFORE, Plaintiff Diane Starkey demands judgment against Defendants Sanofi S.A.; Aventis Pharma S.A.; and Sanofi-Aventis U.S. LLC, separately and doing business as Winthrop U.S. in an amount to be determined at trial by the trier of fact for her injuries, harms, damages, and losses as set forth above, special damages, treble damages, costs, expert witness fees, attorneys' fees, filing fees, pre- and post-judgment interest, all other injuries and damages as shall be proven at trial, and such other further relief as the Court may deem appropriate, just, and proper.

JURY DEMAND

Plaintiff demands a trial by jury on all issues so triable.

Dated: September 16, 2016

GOMEZ TRIAL ATTORNEYS

/s/ Ahmed S. Diab
JOHN H. GOMEZ
jgomez@gomeztrialattorneys.com
AHMED S. DIAB
adiab@gomeztrialattorneys.com
LINDSAY R. STEVENS
lstevens@gomeztrialattorneys.com
655 W. Broadway Suite 1700
San Diego, California 92101
Telephone: (619) 237-3490
Facsimile: (619) 237-3496

BACHUS & SCHANKER, LLC

kyle.bachus@coloardolaw.net
1899 Wynkoop Street, Suite 700
Denver, CO 80202
Telephone: (303) 893-9800
Facsimile: (303) 893-9900
(Pending Pro Hac Vice)

Attorneys for Plaintiff Diane Starkey